Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis B Surface Antibody EIA
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86706
Synonyms	Antibody to Hepatitis B Surface Antigen, Anti-HBs
Brief Description of Test	The Bio-Rad MONOLISA™ Anti-HBs EIA is used for the detection of antibody to hepatitis B surface antigen in human serum. The assay results may be used as an aid in the determination of susceptibility to hepatitis B virus (HBV) infection in individuals prior to or following HBV vaccination or where vaccination status is unknown. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. A reactive assay result will allow a differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.
Possible Results	Nonreactive Borderline Reactive
Reference Range	Reactive
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	275 µL
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. Follow the package insert for the collection tube you use.

	Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens must be shipped refrigerated (2-8°C) and can be stored for up to 7 days. For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.
Causes for Rejection	Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements must also be rejected.
Limitations of the Procedure	For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. A nonreactive test result does not exclude the possibility of exposure to hepatitis B virus. Results obtained with the MONOLISA™ Anti-HBs EIA assay may not be used interchangeably with values obtained with different manufacturers' anti-HBs assay methods. Results from immunosuppressed patients should be interpreted with caution. This assay does not differentiate between a vaccine-induced immune response and an immune response induced by infection with HBV. To determine if the anti-HBs response is due to vaccine or HBV infection, a total anti-HBc assay may be performed. Performance characteristics have not been established for therapeutic monitoring. A reactive anti-HBs result does not exclude co-infection by another hepatitis virus.

	Individuals that have received blood component therapy (e.g., whole blood, plasma, immune globulin administration) during the previous 3 to 6 months may have a false reactive anti-HBs result due to passive transfer of anti-HBs. The performance of the MONOLISA™ Anti-HBs EIA has not been established with cord blood, neonatal specimens, cadaver specimens, heat-inactivated specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids.
Interfering Substances	None listed in the package insert
References	BioRad MONOLISA™ Anti-HBs EIA Package Insert. EVOLIS™ Operator Manual
Additional Information	None
Release Date	03/15/2016
Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.	